Montana
Perinatal Hepatitis B Prevention Program Manual

Montana Department of Public Health and Human Services

Immunization Program

Introduction

This manual provides guidance to local public health professionals and the medical community on the standard practices of the Montana Perinatal Hepatitis B Prevention Program. The guidance provided in this manual is based on current Advisory Committee for Immunization Practices (ACIP) recommendations[1] and complies with State public health law (see Appendix A).

The goal of the Montana Perinatal Hepatitis B Prevention Program is to prevent transmission of hepatitis B virus (HBV) from mother to infant (perinatal transmission) by:

- Identifying HBsAg positive pregnant women,
- Ensuring administration of the birth dose of hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours of delivery to infants born to HBsAg positive women, and follow-up for completion of the hepatitis B vaccine series and post-serologic testing
- Supporting local health departments to identify, evaluate, and manage household, needle-sharing, and sexual contacts of HBsAg positive pregnant women for hepatitis B virus (HBV)
- Coordinating/Assisting with the transfer of healthcare information between:
  - Laboratories
  - Primary care providers
  - Hospitals
  - Local and state health departments
- Promoting the administration of the birth dose of hepatitis B vaccine to all infants before hospital discharge

The Montana Perinatal Hepatitis B Prevention Program is administered by the Montana Department of Public Health and Human Services (MT DPHHS) Immunization Program and funded by the Centers for Disease Control and Prevention (CDC).

Key program contacts:

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http://www.dphhs.mt.gov/publichealth/lab/index.shtml

[1] See the 12/23/05 MMWR: "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States" for the latest Advisory Committee on Immunization Practices (ACIP) recommendations, at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm.

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Key Points for Perinatal Hepatitis B Prevention

The following key points incorporate ACIP recommendations (published December 23, 2005), and pertinent Montana Administrative Rules and Code (Appendix A).

Maternal hepatitis B surface antigen (HBsAg) testing:

- All pregnant women must be tested for HBsAg during each pregnancy MCA 50.19.103 (Appendix A).
- Montana Administrative Rule 37.114.540 (Appendix A) mandates follow-up of positive HBsAg results, and prophylactic treatment of all infants born to HBsAg positive women.
- All women who are in a high-risk category (defined in Appendix B) should be re-tested for HBsAg at the time of admission to the birthing hospital.

Reporting and tracking HBsAg positive women:

- All HBsAg positive pregnant women must be reported to the local health department (LHD). The LHD will notify the Montana Perinatal Hepatitis B Prevention Program.
- Infants born to HBsAg positive mothers and all household, sexual, and needle sharing contacts must be identified and case-managed by the local health department.

Vaccination of infants at birth

If mother is HBsAg positive:

- Infants born to HBsAg positive mothers should receive hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth.
- For preterm infants weighing <2,000 grams, the initial dose of vaccine is not counted toward the three-dose vaccine series (Appendix B).

If mother has unknown HBsAg status:

- Infants born to mothers with an unknown HBsAg status should receive hepatitis B vaccine within 12 hours of birth.
- The mother should have a blood specimen tested as soon as possible to determine her HBsAg status.
- If the mother is found to be HBsAg positive the infant should receive HBIG as soon as possible, but no later than seven days after birth.
- Because of the vaccine's potential for decreased immunogenicity in preterm infants, those infants weighing < 2,000grams should receive both hepatitis B vaccine and HBIG if the mother's HBsAg status cannot be determined ≤12 hours of birth.

***If mother is HBsAg negative*:**

- All birthing hospitals should implement standing orders for the administration of hepatitis B vaccine for all medically stable infants weighing >2,000 grams.
- Only in rare circumstances, and on a case-by-case basis, may the first dose of hepatitis B vaccine be delayed until after hospital discharge.
- Preterm infants weighing < 2,000 grams should receive the first dose of vaccine one month after birth or at hospital discharge (Appendix B).

Follow up vaccine doses and post-vaccine serology:

- All infants should complete the vaccine series with either single-antigen vaccine or combination vaccine, according to the recommended vaccine schedule.
- Infants born to HBsAg positive mothers should be tested for both HBsAg and hepatitis B surface antibody (anti-HBs) titer after completion of vaccine series, between age 9–18 months, but no sooner than age 9 months.

Roles and Responsibilities

The following roles and responsibilities within the Montana Perinatal Hepatitis B Prevention Program ensure compliance with State public health law and ACIP recommendations:

State Health Department

Montana Immunization Program

- Administers the Montana Perinatal Hepatitis B Prevention Program
- Oversees case management statewide of HBsAg positive pregnant women and their infants
- Provides education, support, and tracking to ensure HBIG and hepatitis B vaccine series completion and serologic testing of infants born to HBsAg positive mothers
- Provides education and consultation to local health departments, birthing hospitals, and healthcare providers regarding HBsAg positive pregnant women and their contacts
- Maintains a statewide database of perinatal hepatitis B cases and provides summary data and reports to the Centers for Disease Control and Prevention (CDC)
- Ensures routine vaccination of all infants with the hepatitis B vaccine series, with the first dose administered at birth
  - Supplies birth dose of hepatitis B vaccine to all infants born in Montana (birthing hospitals must be enrolled in the Vaccines for Children [VFC] Program)
  - Supplies hepatitis B vaccine primary series to eligible children
- Supplies HBIG to birthing hospitals for administration to infants born to HBsAg positive women

Montana Public Health Laboratory (MTPHL)

- Provides routine testing weekly for HBsAg and anti-HBs titers
- Provides STAT HBsAg testing if the laboratory is notified in advance
- For mothers with no HBsAg results, the lab provides STAT testing results 1–2 days after receiving specimen to ensure timely delivery of HBIG to infants born to HBsAg positive mothers

Local Health Department (in the county where the infant resides)

- Provides case management to ensure HBIG delivery and notification of birthing hospital staff 6–8 weeks prior to the estimated date of delivery for a HBsAg positive mother
- Ensures completion of the hepatitis B vaccine series and post-vaccination serology for the infant
- Reports to the Montana Perinatal Hepatitis B Prevention Program all data regarding administration of follow-up doses of vaccine and post-vaccination serology of the infant
- Identifies, evaluates, and manages follow-up of household, sexual, and needle-sharing contacts of HBsAg positive mothers

Healthcare Workers

Laboratory Staff:

- Reports all HBsAg positive results **(including repeat testing, even if the results have been previously reported)** immediately to the local health department (LHD) in the county where the patient resides
- Reports all HBsAg results to the ordering physician

Prenatal Care Provider:

- Tests every pregnant woman during each pregnancy for HBsAg **even if they have been previously vaccinated or tested**
- Informs all pregnant women of their HBsAg status
- Sends a copy of the HBsAg test result for current pregnancy with prenatal records to the birthing hospital
- Reports all HBsAg positive pregnant women to the LHD immediately **(even if they were previously reported)**
- Counsels HBsAg positive pregnant women about their status and refers for appropriate care
- Assesses HBsAg negative pregnant women for their risk of acquiring hepatitis B virus (HBV) infection
- Counsels HBsAg negative pregnant women on methods to prevent HBV transmission
- Vaccinates pregnant HBsAg negative women if high risk
- Retests high-risk HBsAg negative pregnant women upon admission to the birthing hospital (Appendix B)

Hospital Labor and Delivery Unit or Nursery Unit Staff:

- Reviews and places a copy of the maternal HBsAg test result for the **current pregnancy** on both the mother's and infant's chart
  - Tests pregnant women for HBsAg STAT if HBsAg status unknown or has risk factors for infection
  - If STAT test is HBsAg positive, reports to the LHD immediately **(even if previously reported)**
- Gives all infants single-antigen hepatitis B vaccine at birth
- Gives all infants born to HBsAg positive women single-antigen hepatitis B vaccine and HBIG within 12 hours of birth
- Reports the administration of HBIG and hepatitis B vaccine on the Hospital Report form and return/fax to the LHD within 7 days of delivery
- Reports all HBsAg positive women to the LHD **(if you were not contacted prior to delivery, the LHD may not be aware of mother's HBsAg status)**

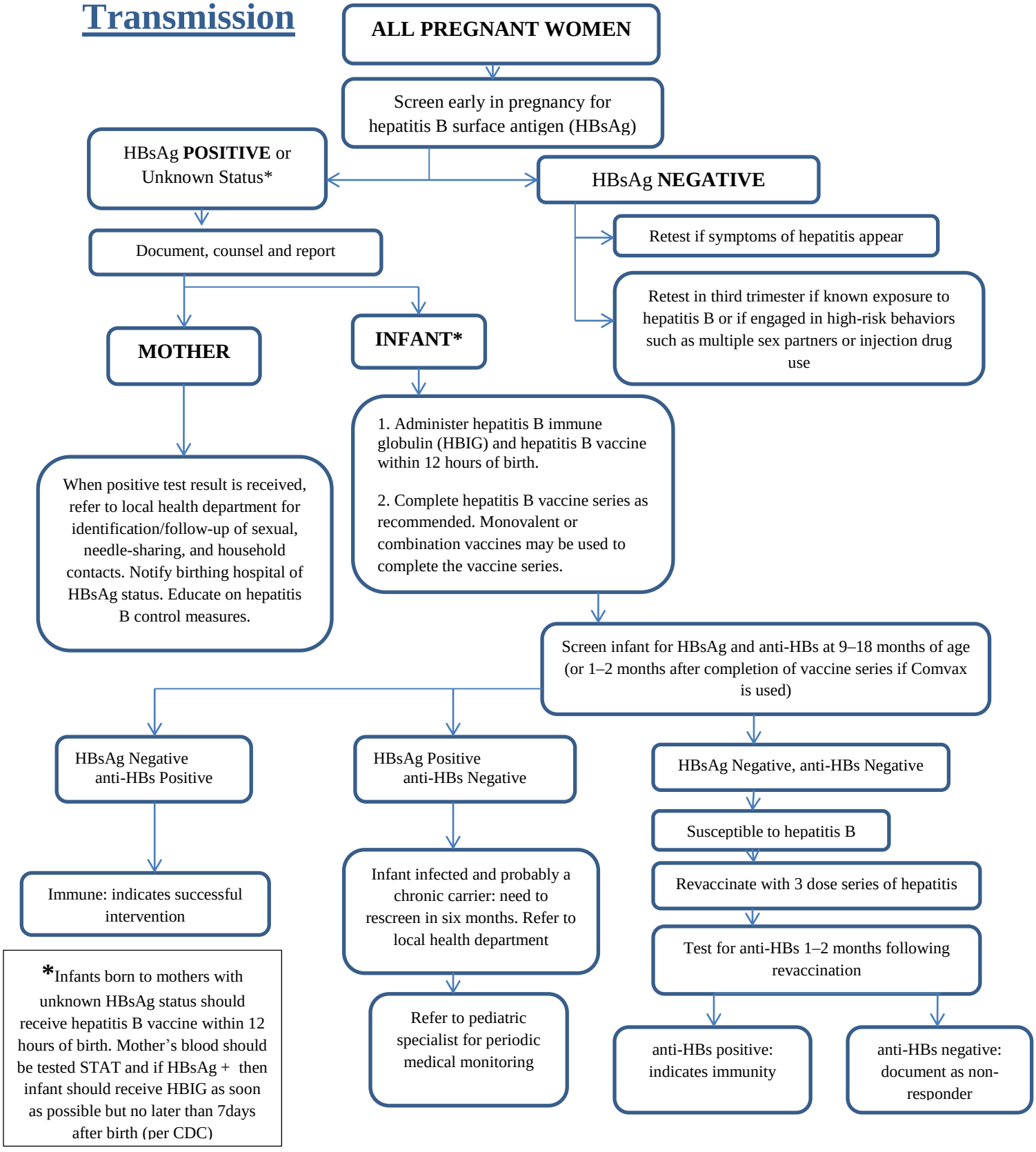
Pediatric Care Provider:

- Knows the maternal HBsAg status for all infants to whom you provide care **(if mom is HBsAg positive and you were not contacted by the LHD, they may not be aware of her status and will need to be notified)**
- Completes the recommended infant **hepatitis B vaccine series** and **post-vaccination serology (HBsAg and anti-HBs titer)** for all infants born to HBsAg positive women (faxes the Infant Report form to the LHD after each dose)
  - If infant is HBsAg negative and anti-HBs negative, repeats a three-dose series of hepatitis B vaccine and retests one month later
  - If the infant is HBsAg positive, counsel the family about the positive test result and refer the infant for appropriate care
- Reports the final hepatitis B vaccine administration and post-vaccination serology results on the Infant Report form and fax to the LHD.

Healthcare provider to a person with at-risk contact to a HBsAg positive pregnant woman:

- Identifies household, needle-sharing, and sexual contacts of HBsAg positive pregnant woman
- Recommends prevaccination testing for susceptibility of unvaccinated household, sexual and needle-sharing contacts of HBsAg positive persons (See Appendix D)
  - Assesses immunization status for all contacts and/or need for HBIG
  - Tests previously unvaccinated contacts *(draws blood prior to administering the vaccine)
  - Treats per recommendations
- Notifies the LHD to provide case management services
- Counsels HBsAg positive contacts regarding risk and refers them for appropriate medical care

Prevention Algorithm–Perinatal Hepatitis B Transmission



Reporting

Montana Law (see Appendix A)

Perinatal Hepatitis B Program Forms

http://www.dphhs.mt.gov/publichealth/immunization/perinatalhepatitisb.shtml

All forms can be found at the link above

1. Perinatal Hepatitis B Forms for Local Health Departments
2. Montana DPHHS Communicable Disease Case Report Form
3. Primary Report for HBsAg Positive Pregnant Women
4. Contact Investigation Line List
5. Hospital/Birth Facility Report Form
6. Infant Report

Appendix A–Montana Administrative Rules and Law

Administrative Rules

37.114.501 MINIMAL CONTROL MEASURES

(1) This subchapter contains minimal control measures to prevent the spread of disease. The local health officer or the officer's designee must either employ the minimal control measures or ensure that a representative of the department when assisting a local health officer with a case, a health care provider treating a person with a reportable disease, or any other person caring for a person with a reportable disease does so, with the exception that if a particular control measure specifies who is responsible for carrying it out, only that person is responsible.

(2) If a reportable disease is not listed in this subchapter, no minimum control measures for the disease are required.

History: 50-1-202, 50-2-116, 50-2-118, MCA; IMP, 50-1-202, 50-2-116, 50-2-118, MCA; NEW, 1980 MAR p. 1579, Eff. 6/13/80; AMD, 1987 MAR p. 2147, Eff. 11/28/87; AMD, 1998 MAR p. 2493, Eff. 9/11/98; AMD, 2000 MAR p. 2528, Eff. 9/22/00; TRANS, from DHES, 2002 MAR p. 913.

37.114.540 HEPATITIS TYPE B (ACUTE OR CHRONIC)

(1) For a case of type B hepatitis:

(a) Infection control precautions must be imposed until it is determined that viremia no longer exists.

(b) The local health officer designee must identify contacts and advise them how to prevent acquisition of the disease, given the nature of their relationship to the case.

(2) In the event a hepatitis B surface antigen (HbsAg) is positive in a pregnant woman, the local health officer must:

(a) ensure appropriate health care providers and the birthing facility are aware of the mother's status and the infant's need for prophylaxis;

(b) ensure that hepatitis B immunoglobulin (HBIG) and vaccine are readily available at the birthing facility at the expected time of delivery;

(c) confirm the administration of HBIG and vaccine after delivery and submit the report form provided by the department within seven days after delivery and counsel the mother and provider regarding the need for further vaccination and testing;

(d) at one to two months and again at six to seven months after delivery contact the health care provider or guardian of the infant to confirm the vaccine was given and provide an update to the department using a form provided by the department; and

(e) at nine to 15 months after delivery, confirm testing of the infant for the surface antigen and antibody to the hepatitis B virus (HBV), counsel as appropriate, and provide an update to the department using a form provided by the department.

History: 50-1-202, 50-2-118, 50-19-101, MCA; IMP, 50-1-202, 50-2-118, 50-19-101, MCA; NEW, 1980 MAR p. 1579, Eff. 6/13/80; AMD, 1987 MAR p. 2147, Eff. 11/28/87; AMD, 2000 MAR p. 2528, Eff. 9/22/00; TRANS, from DHES, 2002 MAR p. 913; AMD, 2006 MAR p. 2112, Eff. 9/8/06.

37.114.201 REPORTERS

(1) With the exception noted in (3) below, any person, including but not limited to a physician, dentist, nurse, medical examiner, other health care practitioner, administrator of a health care facility, public or private school administrator, or laboratorian who knows or has reason to believe that a case exists shall immediately report to the local health officer the information specified in ARM 37.114.205(1) through (2).

(2) A local health officer must submit to the department, on the schedule noted in ARM 37.114.204, the information specified in ARM 37.114.205 concerning each confirmed or suspected case of which the officer is informed.

(3) A state funded anonymous testing site for HIV infection is not subject to the reporting requirement in (1) with regard to HIV testing.

History: 50-1-202, 50-17-103, 50-18-105, MCA; IMP, 50-1-202, 50-2-118, 50-17-103, 50-18-102, 50-18-106, MCA; NEW, 1980 MAR p. 1579, Eff. 6/13/80; AMD, 1986 MAR p. 254, Eff. 2/28/86; AMD, 1987 MAR p. 2147, Eff. 11/28/87; AMD, 1995 MAR p. 1127, Eff. 6/30/95; AMD, 2000 MAR p. 2528, Eff. 9/22/00; TRANS, from DHES, 2002 MAR p. 913; AMD, 2006 MAR p. 2112, Eff. 9/8/06.

History: En. Sec. 3, Ch. 228, L. 1973; R.C.M. 1947, 69-6703(2); amd. Sec. 13, Ch. 440, L. 1989; amd. Sec. 6, Ch. 351, L. 2001.

Montana Law: Montana Code Annotated

50-19-101. Definitions. As used in this part, the following definitions apply:

(1) "Department" means the department of public health and human services provided for in 2-15-2201.

(2) "Health care provider" means a licensed physician, a physician assistant, a registered nurse, an advanced practice registered nurse, a naturopathic physician, or a direct-entry midwife practicing within the scope of the provider's professional license.

(3) "Standard serological test" means a test for syphilis, rubella immunity, and blood group, including ABO (Landsteiner blood type designation--O, A, B, AB) and RH (Dd) type, and a screening for hepatitis B surface antigen, approved by the department.

History: En. Sec. 1, Ch. 228, L. 1973; amd. Sec. 25, Ch. 187, L. 1977; R.C.M. 1947, 69-6701; amd. Sec. 119, Ch. 418, L. 1995; amd. Sec. 296, Ch. 546, L. 1995; amd. Sec. 2, Ch. 351, L. 2001; amd. Sec. 26, Ch. 519, L. 2005; amd. Sec. 85, Ch. 2, L. 2009.

50-19-103. Prenatal blood sample required for serological test. (1) Every female, regardless of age or marital status, seeking prenatal care from a health care provider is required to submit a blood specimen for the purpose of a standard serological test. In submitting the specimen to the laboratory, the health care provider shall designate it as a prenatal test.

(2) A health care provider who attends a pregnant woman shall at the first professional visit take the blood sample and submit it to a laboratory.

(3) A person permitted to attend a pregnant woman, but not permitted to take blood samples, must have the sample taken by a person permitted to take blood samples and submit it to a laboratory.

(4) A health care provider who violates this part is guilty of a misdemeanor. However, a health care provider who requests a sample of blood in accordance with this provision and whose request is refused is not guilty of a violation of this section.

History: En. Sec. 2, Ch. 228, L. 1973; R.C.M. 1947, 69-6702; amd. Sec. 4, Ch. 351, L. 2001.

50-19-104. Approved laboratory to perform syphilis, hepatitis B surface antigen, and rubella immunity tests**.** (1) The tests for syphilis, hepatitis B surface antigen, and rubella immunity must be done by the laboratory of the department, a laboratory approved by the department, any other state laboratory, or a United States public health service or armed forces laboratory.

(2) The department may establish a reasonable fee for the tests done by the department laboratory.

History: En. Sec. 3, Ch. 228, L. 1973; R.C.M. 1947, 69-6703(part); amd. Sec. 1, Ch. 72, L. 1985; amd. Sec. 5, Ch. 351, L. 2001.50-19-105. Report of positive test results. All positive laboratory tests for any sexually transmitted diseases or hepatitis B surface antigen must be reported to the department by the laboratory preparing the test. The department shall prescribe the form and way of reporting.

50-19-105. Report of positive test results**.** All positive laboratory tests for any sexually transmitted diseases or hepatitis B surface antigen must be reported to the department by the laboratory preparing the test. The department shall prescribe the form and way of reporting.

History: En. Sec. 3, Ch. 228, L. 1973; R.C.M. 1947, 69-6703(2); amd. Sec. 13, Ch. 440, L. 1989; amd. Sec. 6, Ch. 351, L. 2001.

Appendix B–Special Circumstances

Infants Weighing <2,000 Grams

Hepatitis B Immunization Management of Preterm Infants Weighing <2,000 g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status

Maternal HBsAg Status	Recommendation
Positive	• Administer HBIG* + single-antigen hepatitis B vaccine within 12 hrs of birth. • Do not count the birth dose as part of the vaccine series. • Administer 3 additional hepatitis B vaccine doses with -single-antigen vaccine at ages 1, 2–3, and 6 mos, *or* -hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).† • Test for HBsAg and antibody to HBsAg 1–2 mos after completion of ≥3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 mos, generally at the next well-child visit). Testing should not be performed before age 9 mos nor within 4 wks of the most recent vaccine dose.
Unknown	• Administer HBIG + single-antigen hepatitis B vaccine within 12 hrs of birth. • Test mother for HBsAg. • Do not count the birth dose as part of the vaccine series. • Administer 3 additional hepatitis B vaccine doses with -single-antigen vaccine at ages 1, 2–3, and 6 mos, *or* -hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).†
Negative	• Delay first dose of hepatitis B vaccine until age 1 mos or hospital discharge. • Complete the hepatitis B vaccine series with -single-antigen vaccine at ages 2 mos and 6–18 mos, *or* -hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).†

* Hepatitis B immune globulin.

† The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

www.cdc.gov/hepatitis

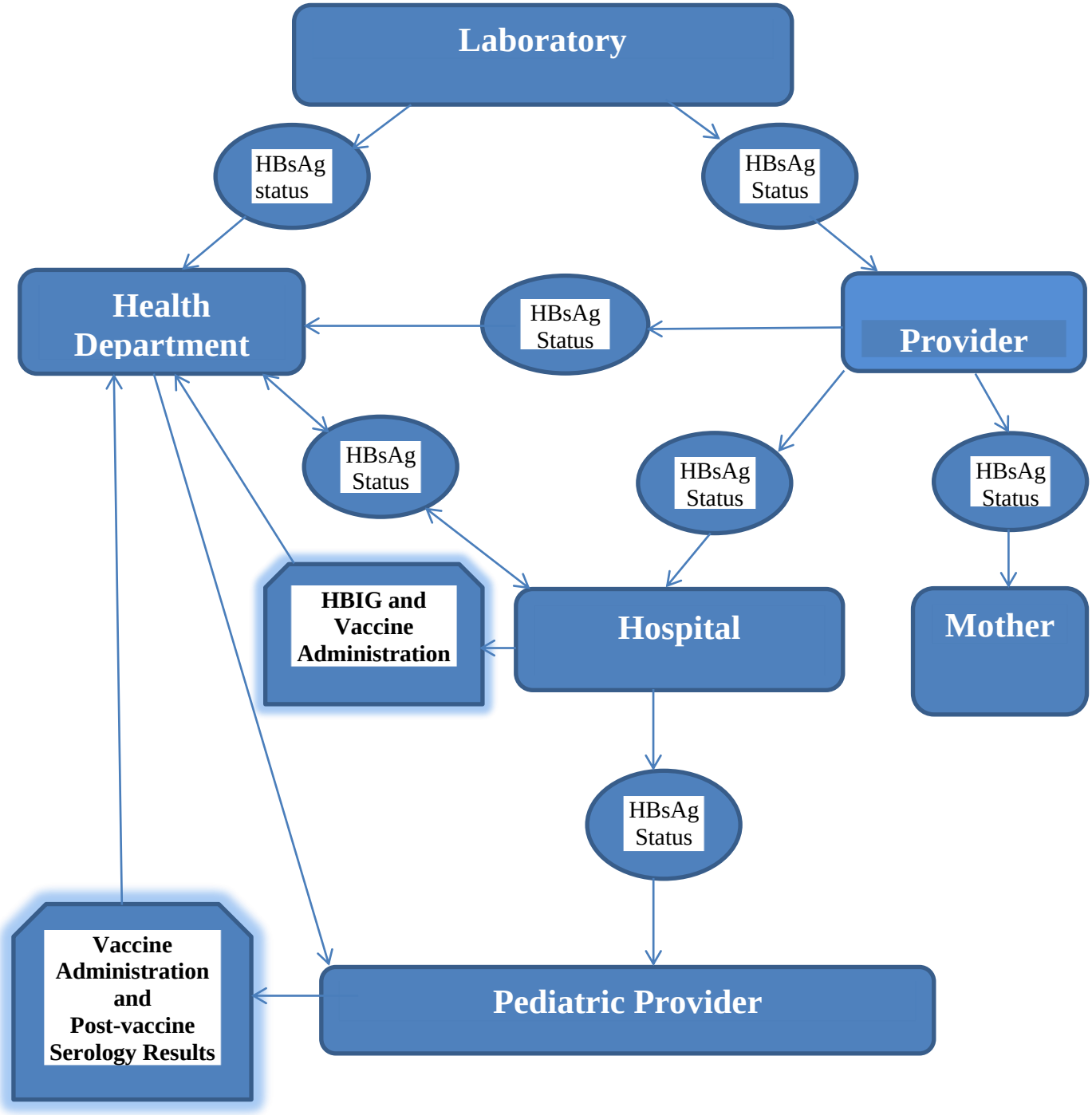
High Risk Categories

(All women who are in a hepatitis B high-risk category should be re-tested at the time of admission to the birthing hospital)

- Persons with multiple sex partners
- Persons with a sexually transmitted disease
- Injection drug users
- Household contacts of infected persons
- Healthcare and public safety workers exposed to blood on the job
- Hemodialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to regions with intermediate or high rates of Hepatitis B (HBsAg prevalence of ≥2%)

http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable.pdf

Appendix C–Laboratory Information Flow



Appendix D–Testing and Management

Prevaccination Serologic Testing for Susceptibility

- Because of the low prevalence of HBV infection among infants, children, and adolescents born in the United States, prevaccination testing for susceptibility usually is not indicated for these age groups.
- Prevaccination testing for susceptibility is recommended for unvaccinated household, sexual, and needle-sharing contacts of HBsAg-positive persons.
- Anti-HBc is the test of choice for prevaccination testing.
- Persons tested for anti-HBc and found to be anti-HBc negative are susceptible and should complete the vaccine series.
- Persons found to be anti-HBc positive should be tested for HBsAg. HBsAg testing may be performed on the same specimen collected for anti-HBc testing. If the HBsAg test result is positive, the person should receive appropriate management (see Appendix A).
- In most situations, the first vaccine dose should be administered immediately after collection of the blood sample for serologic testing.

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a3.htm?s_cid=rr5416a3_e

Recommendations for management of persons who are exposed to HBV through a discrete, identifiable exposure to blood or body fluids that contain blood

HBsAg-Positive Source

- Unvaccinated persons or persons known not to have responded to a complete hepatitis B vaccine series should receive both hepatitis B immune globulin (HBIG) and hepatitis B vaccine as soon as possible after exposure (preferably ≤24 hours). For sexual exposures, HBIG should not be administered more than 14 days after exposure. Hepatitis B vaccine may be administered simultaneously with HBIG in a separate injection site. The hepatitis B vaccine series should be completed using the age-appropriate vaccine dose and schedule.
- Persons who are in the process of being vaccinated but who have not completed the vaccine series should receive the appropriate dose of HBIG and should complete the vaccine series.
- Children and adolescents who have written documentation of a complete hepatitis B vaccine series and who did not receive post-vaccination testing should receive a single vaccine booster dose.

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a4.htm?s_cid=rr5416a4_e

http://www.cdc.gov/hepatitis/HBV/PerinatalXmtn.htm

Resources

Websites

Montana Immunization Program
http://www.dphhs.mt.gov/publichealth/immunization/

A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e

Centers for Disease Control and Prevention, Hepatitis B Information for Health Professionals
http://www.cdc.gov/hepatitis/HBV/PerinatalXmtn.htm

Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm

Immunization Action Coalition, Handout for Health Care Professionals: Give the Birth dose
http://www.immunize.org/catg.d/p2125.pdf

Asian Liver Center, Stanford School of Medicine, Brochure: *Hepatitis B and Moms-to-be*
http://liver.stanford.edu/Media/publications/Pregnancy/English.pdf

State Program Manuals

Perinatal Hepatitis B Prevention Program Manual
Michigan Department of Community Health

Perinatal Hepatitis B Prevention Program Manual [PDF - 83 pages]
New York State Department of Health

Perinatal Hepatitis B Prevention Program Manual
Texas Department of State Health Services